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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,054	11/01/2000	Robert D'Amato	9516-039-999	3798

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EXAMINER
ANDERSON, JAMES D

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
10/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/704,054	D'AMATO, ROBERT	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,29,73,76 and 77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,29,73,76 and 77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/9/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Applicants' response and amendments to the claims, filed 9/9/2010, are acknowledged and entered. Claims 23, 29, 73, and 76-77 are pending and under examination.

Response to Arguments

Applicants' arguments, filed 9/9/2010, have been fully considered and are persuasive in part. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 9/9/2010. The Examiner has considered the references cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

Claim Rejections - 35 USC § 112 – 1st Paragraph, New Ground of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 29, 73, and 76-77 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1st "Written Description" Requirement, Federal

Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001. **This is a New Matter rejection**.

The claims are drawn to methods of treating a blood-born tumor (claims 23 and 77) or leukemia (claim 73) in a patient comprising administration of thalidomide, "wherein said patient does not have graft-versus-host disease". The amended claims thus exclude particular patients, *i.e.*, patients having a blood-born tumor (*e.g.*, leukemia) but who do not have graft-versus-host disease. There is no basis in the originally filed disclosure for the specific exclusion of such patients from the claimed treatment methods.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117).

Applicant relies on the originally filed specification at page 5, lines 12-19, page 8, lines 3-12, page 9, lines 7-9, and page 20, lines 20-24 as providing support for exclusion of patients having blood-born tumors but who do not have graft-versus-host disease. The cited sections of the originally filed specification are reproduced below for ease of discussion.

> "...retinoblastoma, Ewing sarcoma, neuroblastoma, and osteosarcoma. A tumor cannot expand without a blood supply to provide nutrients and remove cellular wastes. Tumors in which angiogenesis is important include solid tumors, and benign tumors such as acoustic neuroma, neurofibroma, trachoma and pyogenic granulomas. Prevention of angiogenesis could halt the growth of these tumors and the resultant damage to the animal due to the presence of the tumor" --- **page 5, lines 12-19 of originally filed specification**

> "Thus, a method and composition are needed that are capable of inhibiting angiogenesis and which are easily administered. A simple and efficacious method of treatment would be through the oral route. If an angiogenic inhibitor could be given by an oral route, the many kinds of diseases discussed above, and other angiogenic dependent pathologies, could be treated easily. The optimal dosage could be distributed in a form that the patient could self-administer" --- **page 8, lines 3-12 of originally filed specification**

> "It is another object of the present invention to provide a treatment for diseases mediated by angiogenesis" --- **page 9, lines 7-9 of originally filed specification**

> "...e.g. Shealy et al., Chem. Indus. 1030 (1965); and Casini et al., Farmaco Ed. Sci. 19:563 (1964). The compounds described above can be provided as pharmaceutically acceptable formulations using formulation methods known to

> those of ordinary skill in the art." --- **page 20, lines 20-24 of originally filed specification**

None of the cited sections of the originally filed specification provide support for exclusion of patients having a blood-born tumor but who do not have graft-versus-host disease.

Applicant further cites column 12, lines 10-12 of U.S. Patent No. 5,629,327[1] as providing support exclusion of the recited patient population. In context, the cited section of USP No. 5,629,327 states, "The epoxide containing angiogenesis inhibitors, with or without epoxide hydrolase inhibitors, are also effective in treating diseases such as septic shock, leprosy and graft vs. host disease". This same language is found in the instant specification at page 19, lines 12-15. Nowhere does the cited section suggest that Applicant contemplated treating patients having a blood-born tumor but who did not have graft-versus-host disease as recited in the amended claims.

Accordingly, exclusion of patients having a blood-born tumor but who do not have graft-versus-host disease is not supported by the originally filed disclosure.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Response to Arguments

Applicant traverses the instant rejection, stating that the instant specification provides ample teaching of the "claimed subject matter". In support of this assertion, Applicant points to the specification at page 5, lines 20-27, which states:

> "It should be noted that angiogenesis has been associated with blood-born tumors such as leukemias, any of various acute or chronic neoplastic diseases of the bone marrow in which unrestrained proliferation of white blood cells occurs, usually accompanied by anemia, impaired blood clotting, and enlargement of the lymph nodes, liver, and spleen. It is believed that angiogenesis plays a role in the abnormalities in the bone marrow that give rise to leukemia-like tumors."

[1] The instant application claims priority to U.S. Non-Provisional Application No. 08/168,817, which issued as U.S. Patent No. 5,629,327.

Applicant further points to the specification at page 9, lines 17-19 which states as follows:

> "It is yet another object of the present invention to provide a method and composition for the treatment of blood-born tumors such as leukemia."

In view of these sections of the specification, Applicant states that a person of ordinary skill would view the specification as providing sufficient written description support for "treatments of blood-born tumors and leukemia".

In response the Examiner does not dispute that Applicant describes methods of treating blood-born tumors and leukemia. The instant rejection is based on the lack of written support for the specific patient population(s) recited in the instant claims, *i.e.*, patients with blood-born tumors or leukemia **who do not have graft-versus-host disease**. That Applicant does not describe methods of treatment relating to treating graft-versus-host disease does not provide written basis for excluding such patients from the instantly claimed invention.

In re Smith, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads). In the instant case, Applicant discloses treatment of a genus of patients, i.e., patients having blood-born tumors or leukemia. Disclosure of such a genus of patients does not implicitly describe the claimed sub-genus/species of patients, i.e., patients with blood-born tumors or leukemia **who do not have graft-versus-host disease**. There is nothing in the specification that would lead one skilled in the art to conclude that Applicant contemplated excluding leukemia patients who have graft-versus-host disease from the treatment methods disclosed in the instant specification.

Applicant argues that he invented and wishes to claims treatment of blood-born tumors via anti-angiogenesis and that he is claiming treatment of patients having blood-born tumors, not graft-versus-host disease. Respectfully, this is not what Applicant is claiming. Applicant is claiming treating a blood-born tumor or leukemia in a patient, wherein said patient does not have graft-versus-host disease. This is a very specific patient population. These are not simply patients with blood-born tumors or leukemia as originally disclosed by Applicant.

The prior art teaches, suggests, and motivates treating leukemia patients having graft-versus-host disease comprising administration of thalidomide. The Examiner previously applied prior art against claims that encompassed the patients taught in the prior art. Applicant

subsequently amended the claims to exclude these specific patients from his invention in order to overcome the prior art. However, as discussed *supra*, exclusion of these specific patients from the claimed methods is new matter. Contrary to Applicant's assertions, one skilled in the art would **not** understand that Applicant intended that leukemia patients having graft-versus-host disease would be excluded from his invention of treating blood-tumors or leukemia.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 23, 29, and 76-77 under 35 U.S.C. 103(a) as being unpatentable over **Olson *et al***. (Clinical Pharmacology and Therapeutics, 1965, vol. 6, no. 3, pages 292-297) are **withdrawn** in light of Applicant's arguments, the Declarations of Professor Morgan and Dr. Ohno, and Applicant's evidence of unexpected results previously submitted.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejections of claims 23, 29, 73, and 76-77 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 6 of U.S. Patent No. 7,435,745 and claims 23, 29, 73, and 76-77 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-30 of copending Application No. 12/249,847 are **withdrawn** in light of Applicant's filing of Terminal Disclaimers on 9/9/2010.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Primary Examiner, Art Unit 1614

October 18, 2010